

Health ABC Analysis Proposal and Publications Guidelines

A. Goals

A.1. To encourage high quality publications and presentations produced in a timely fashion.

B. Scope of the guidelines

B.1. These guidelines apply to investigators affiliated with Health ABC and to those without an affiliation with Health ABC who are proposing any form of analysis, publication, or report that describes Health ABC methodology or utilizes core or ancillary study data collected.

B.2. These guidelines apply to papers (including methodology and validation papers), and letters to the editor that use data collected as part of the core Health ABC study or ancillary study data (refer to Health ABC Ancillary Study Guidelines).

B.3. These policies remain in force after funding for the study ends.

C. Types of publications

C.1. These guidelines broadly cover any publication or report that describes Health ABC methodology or utilizes core or ancillary study data.

C.2. The guidelines encompass four different types of publications:

C.2.1. Study-wide papers reporting Health ABC data collected from both field centers.

C.2.2. Local papers reporting data collected from locally initiated and separately funded ancillary studies that are unique to one site or any other paper using subsets of data from the study.

C.2.3. Methodology/validation papers.

C.2.4. Letters to the editor reporting Health ABC data collected from one or both of the field centers.

D. Authorship

D.1. Authors should participate in the writing of the paper in accordance with the International Committee of Medical Journal Editors guidelines (N Engl J Med 1991;324:424-8).

D.2. Authorship of papers and abstracts:

D.2.1 An individual investigator will be limited to lead author on three active analysis proposals (“active” defined as the manuscript not yet submitted for publication).

D.2.2. All study-wide papers, abstracts, and presentations (oral and poster) should include “for the Health ABC Study” in the authorship line.

D.3. Collaboration:

D.3.1. Publications resulting from study-wide analyses are expected to have at least one Health ABC investigator as a sponsor.

D.3.2. Lead authors are responsible for assembling the group of co-authors and for determining the order of authorship. Authorship should be ordered by contribution to the conceptualization, analysis and writing of the paper.

D.3.3. Lead authors are responsible for distributing all publication materials, including manuscripts, letters to the editors, etc., to all co- authors for review prior to submission.

D.3.4. Lead authors are expected to delete names from the final list of authors if those individuals have not participated in the writing and/or analysis of the paper in accordance with the International Committee of Medical Journal Editors guidelines.

E. Official study name, required acknowledgements, and recommended terminology

E.1. The official name of the study for scientific purposes is the “Health, Aging, and Body Composition Study.” When referring to the Health ABC Study in the text of an abstract or paper, refer to it as the “Health, Aging, and Body Composition Study.” If space is an issue, refer to the study as the “Health ABC Study.”

E.2. Papers, abstracts, and presentations (oral and poster) should list the NIA contract and grant numbers that have provided core support to the project in an “Acknowledgement”. Additional grants should also be included as pertinent to the specific paper, abstract or presentation. The following statement includes the major sources of funding, and will meet this requirement:

This research was supported by National Institute on Aging (NIA) Contracts N01-AG-6-2101; N01-AG-6-2103; N01-AG-6-2106; NIA grant R01-AG028050, and NINR grant R01-NR012459. This research was funded in part by the Intramural Research Program of the NIH, National Institute on Aging.

E.4. Use of data from the DXA validation studies, Health ABC QDR 4500, and whole body phantoms should acknowledge support from Hologic, Inc.

E.5. All papers, abstracts, and presentations should use the following terminology conventions: race (instead of ethnicity, since ethnicity was not measured in Health ABC) and Black/White when referring to race.

F. Analysis Plans

F.1. Submitting Analysis Plans

F.1.1. All investigators planning projects or publications (including study-wide and local papers, methodology/validation papers, letters to the editor) utilizing Health ABC core or ancillary study data must submit an analysis plan.

F.1.2. Analysis plans should be submitted via e-mail to the Health ABC website. The analysis plan must include:

- a. The name of the first author. If the first author is not affiliated with the study, then a sponsoring Health ABC investigator should also be listed.
- b. A provisional list of potential co-authors.
- c. Statement of the research question(s) or hypothesis.
- d. Brief background and rationale for addressing the research question or hypothesis in Health ABC.
- e. Variables to be used in the analysis; the main predictor and outcome variables should be identified.
- f. A mock-up of key tables.
- g. A timeline for completion and submission of the paper.
- h. Deadlines for submission of abstracts or dates of presentation and meeting (if applicable)
- i. The unit that will be responsible for analyzing the data.

F.1.3. In general, each analysis plan should be designed to result in a single manuscript.

F.1.4. If the objectives of an analysis plan evolve and deviate substantially from the original plan, the first author is responsible for submitting an amended analysis plan.

F.1.5. The role of the Health ABC sponsor is to help with analysis and explain the origin of variables and uses of data. The Health ABC dataset is complex and the sponsor is expected to play an active role as a guide and mentor.

F.2. Review and Approval of Analysis Plans. The process is as follows:

F.2.1. Once an analysis plan is received the analysis plan will be listed on the Health ABC web site within 48 hours of receipt, with a status of “under review.”

F.2.2. Analysis plans will initially be reviewed to check for potential overlap with other plans.

F.2.3. If no or little overlap occurs then the analysis plan will be accepted. If overlap occurs or for other problems, the proposer will be asked to make a revision in the proposal.

F.2.4. After approval, analysis plans will be posted on the secure area of the Health ABC web site and the first author will be notified by email

F.2.5. If the proposal is accepted, the proposer will be asked to submit a completed DUA. This needs to be reviewed at the NIA IRB at several levels.

F.2.6. Once the review is completed, the proposer will be given access to download data and files from the Health ABC website for a pre-determined limited period of time.

G.3. Expiration of Analysis Plans

G.3.1. Plans may also expire and authorship potentially reassigned if a manuscript has not been submitted for publication within 18 months from the date of approval of the analysis plan.

H. Review and approval of papers

H.1. Papers must have an approved analysis plan before the paper is submitted to the for NIA clearance.

H.2. Papers must be reviewed by all co-authors prior to submission for NIA clearance Publications.

H.4. Papers must also receive clearance from the NIA prior to submission for publication.

H.5. The approval process for publication is as follows:

H.5.1. The first author will be responsible for sending the manuscript to all co-authors.

H.5.2. The first author must carefully consider the comments and revise the manuscript incorporating the co-authors suggestions.

H.5.3. The first author will submit an approved paper to the NIA for clearance.

H.5.5. A paper may be submitted for publication when the first author receives an approval email notifying that the NIA has cleared it for publication.

H.5.7. The first author is responsible for sending an electronic copy of the final version of the manuscript to the Health ABC website.

H.5.8. The first author is responsible for sending any programming code for derived

(calculated variables) constructed specifically for the analysis in the paper to the Publications Coordinator.

I. Archives

The NIA Health ABC website will maintain an electronic archive of all Health ABC publications.